

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARRAY BIOPHARMA INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 23-625-GBW
)	
TEVA PHARMACEUTICALS, INC.,)	
)	
Defendant.)	
)	

REPLY BRIEF IN SUPPORT OF DEFENDANT’S MOTION TO STAY

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I. INTRODUCTION

A stay is appropriate at this stage of the case against Teva. Array does not propose that the case proceed on a standard schedule; rather, it proposes two alternatives. According to Array, this Court should either (1) proceed straight to claim construction and allow Array to seek reconsideration of the Court's prior decision or (2) enter final judgment of non-infringement and allow immediate appeal. Neither alternative is appropriate.

The Court should not allow Array to seek reconsideration of this very Court's prior claim construction ruling in the *Alembic* case, here in the case against Teva. Array has offered no reason, other than *ipse dixit* assertions that the Court got it wrong, for why claim construction from the *Alembic* case should be reconsidered in the Teva case. Nor has Array set forth any details for how this case would proceed under its proposal. No schedule has been set in this case; no discovery or contentions have been served; no documents have been produced; and no claim construction exchanges have occurred. Array offers no explanation for how it proposes to proceed or why the Court should hear again the same arguments that it has already rejected providing Array a second bite at the apple.

Array's other proposal, that the Court should "apply its prior claim construction in this case and enter final judgment of non-infringement in Teva's favor, permitting Array to appeal to the Federal Circuit," D.I. 19 at 1, is similarly unavailing. Array does not even attempt to explain why that would be appropriate, let alone fair to Teva, and Array cites absolutely no legal precedent in support of its suggestion. Teva did not participate in *Alembic*, and Teva has no access to the record or discovery in that case. Indeed, were Array permitted to appeal the *Alembic* construction in this case, the record would not contain *any* of the materials on which the Court relied to reach its decision. Array sought no interlocutory appeal in *Alembic* and should not be allowed a covert interlocutory appeal using the action against Teva.

Finally, Array would not be prejudiced by waiting to appeal the *Alembic* construction at the appropriate time, in the appropriate action, with the benefit of the fully developed record. Array waited for over a year to sue Teva after Teva provided notice of the filing of its ANDA. Even after filing suit, Array did little to nothing to move this case forward. And the risk to Array that Teva could launch its product before resolution of the appeal in the *Alembic* case is minimal at most. Teva cannot launch its proposed product for over six years; Array offers no argument why the *Alembic* matter will not be completed by that time. Teva respectfully requests that the Court grant Teva's motion to stay the case pending resolution of any appeal of the claim construction decision in *Alembic*.

II. ARRAY'S ARGUMENTS AGAINST A STAY LACK MERIT

A. Simplification Is Certain, Not Speculative

A stay will simplify this case and preserve both judicial resources and those of the parties. If the Court grants the requested stay, the case can be administratively closed and the Court need do nothing until after resolution of the appeal in the *Alembic* case. That is the epitome of simplification. Array argues that "[a]ny purported simplification of the issues is too speculative to warrant a stay" because "Teva's simplification argument assumes the outcome Teva wants—that the Court's claim construction in *Alembic/Sandoz* will stand." D.I. 19 at 2–3. Array thus admits that the issues in this case will be simplified if the Federal Circuit upholds the Court's construction, as the case against Teva will be resolved. Even if the Federal Circuit were to vacate or modify the construction, the parties and the Court would still have the benefit of the Federal Circuit's analysis of the issues, which would be instructive in any subsequent litigation of the construction in this Court. *See Personal Genomics Taiwan, Inc. v. Pac. Bioscis. of Cal., Inc.*, C.A. No. 19-1810-GBW-MPT, 2022 WL 4245532, at *2 (D. Del. Sept. 15, 2022) ("The Federal Circuit's decision regarding the proper scope of the disputed term ... will likely affect claim

construction, fact discovery, and expert discovery in this case. Judicial efficiencies would be gained by staying this case rather than have this Court and the Federal Circuit address the construction of the same term in parallel.”); *see also Choon’s Design Inc. v. Tristar Prods., Inc.*, C.A. No. 14-10848-VAR, 2018 WL 11351661, at *1–2 (E.D. Mich. July 13, 2018) (stay would simplify the issues because “the Federal Circuit will determine the proper claim construction for terms” in dispute). Array makes a faulty analogy to cases in which petitions for *inter partes* review had been filed but not yet instituted. *See* D.I. 19 at 3–4 (citing cases). Here, the Court has *already* issued its claim construction decision, and under that construction, Teva does not infringe. Allowing the Federal Circuit to review the Court’s claim construction will simplify the issues in this case.

Array also argues that the *Alembic* cases may settle and there would be “no appeal of the claim construction ... and no simplification of the issues in this case.” D.I. 19 at 4. Ironically, it is Array who is speculating. The *Alembic* construction may not be appealed, but that is not a reason to force the parties and the Court to expend significant resources *now*, when what is certain is that the issues in this case have already been resolved by the *Alembic* construction. If the *Alembic* cases settle and the construction is never appealed, the parties can notify the Court and determine how to proceed at that time, if the parties have not settled this action already. In any event, this Court has previously granted stays even when an appeal had not yet been filed. *See, e.g., AgroFresh Inc. v. Essentiv LLC*, C.A. No. 16-662-MN, 2019 WL 2327654, at *1 (D. Del. May 31, 2019).

B. A Stay Will Prevent the Parties and the Court from Wasting Resources

Array argues that “[t]he fact that the *Alembic/Sandoz* case has proceeded through claim construction—and resulted in a construction that would foreclose Array’s claims here against

Teva—effectively makes this case more advanced than the typical case where discovery has yet to begin,” suggesting that “[t]his case is either at the *Markman* stage ... or the case is over.” D.I. 19 at 4–5. But of course, this case is not at the *Markman* stage. Rather, it could hardly be at any earlier stage than the one it is in now—there has been no Rule 16 scheduling conference, no scheduling order has been entered, and no discovery has been served. “Motions to stay like these are most often granted when the case is in the early stages of litigation.” *Princeton Digital Image Corp. v. Konami Digital Ent. Inc.*, C.A. No. 12-1461-LPS-CJB, 2014 WL 3819458, at *3 (D. Del. Jan. 15, 2014); *see also Abbott Diabetes Care, Inc. v. Dexcom, Inc.*, C.A. No. 06-514-GMS, 2007 WL 2892707, at *5 (D. Del. Sept. 30, 2007) (staying litigation where no Rule 16 scheduling conference or discovery had occurred, no scheduling order had been entered, and “little time [had] yet to be invested in the litigation”).

Array suggests that the parties can skip all of the usual steps, and proceed directly to claim construction, and that the case should therefore be treated as one that has advanced to that stage. The stage-of-the-case factor weights against a stay only when “the Court and the parties have already expended significant resources on the litigation, and the principle of maximizing the use of judicial and litigant resources is best served by seeing the case through to its conclusion.” *Princeton Digital*, 2014 WL 3819458, at *3. Here, very limited resources have been expended because the case has not been substantively litigated, save for the instant motion. Even if this case could be “completed expeditiously and with relatively little (if any) discovery,” as Array seems to suggest, the early stage of the case would still favor a stay. *UCB, Inc. v. Zydus Pharms. (USA) Inc.*, C.A. No. 16-903-LPS, 2017 WL 4310860, at *2 (D. Del. Sept. 28, 2017).

Where “discovery is in its nascent stages,” a stay is warranted. *Princeton Digital*, 2014 WL 3819458, at *3; *see also SenoRx, Inc. v. Hologic, Inc.*, C.A. No. 12-173-LPS, 2013 WL

144255, at *5 (D. Del. Jan. 11, 2013) (finding this factor “squarely favors a stay” where defendant had answered the complaint, the Court held a Rule 16(b) teleconference, and a Scheduling Order had issued, but the parties were in the early stages of discovery). Here, absolutely no discovery has been taken. Accordingly, this factor strongly favors a stay.

C. A Stay Would Not Unduly Prejudice Array

Array has identified no prejudice it would suffer if a stay were entered. Array’s only argument for prejudice appears to be that Array “must wait to enforce [its] patent rights.” D.I. 19 at 5. As an initial matter, “[t]he mere potential for delay ... is insufficient to establish *undue* prejudice.” *Neste Oil OYJ v. Dynamic Fuels, LLC*, C.A. No. 12-1744-GMS, 2013 WL 3353984, at *2 (D. Del. July 2, 2013) (emphasis original). But even if the ultimate resolution of this case is delayed by a stay, Array will not be “wait[ing] to enforce [its] patent rights” because there will be no marketed generic product from Teva. D.I. 19 at 5. As Teva explained in its opening brief, Teva does not seek to market its generic product before the expiration of the Huang Patents, the latest of which does not expire until July 2031. *See* Ex. A (Food & Drug Admin., *Patent & Exclusivity for NDA 210498 (Binimetinib)*).¹ Array essentially argues the Court should deny a stay so Array can hurry up and enforce its patents against a product that will not appear on the market until more than six *years* from now. *See AgroFresh*, 2019 WL 2327654, at *3 (where defendant is “not on the market,” patentee is less likely to be unduly prejudiced by stay).

Array’s reliance on *UCB* is misguided. In *UCB*, the Court partially denied a request for a stay to ensure the case could be completed before the expiration of the 30-month regulatory stay. 2017 WL 4310860, at *1–2. Here, there is no 30-month stay because Array did not file its complaint against Teva for nearly a year after Teva sent its notice letter to Array, long after the

¹ Available at https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=210498&Appl_type=N.

45-day window in which the regulatory 30-month stay could have been triggered. In any event, even if this Court were to grant Teva's motion to stay, this case is all but certain to be resolved before Teva brings its generic product to market (a fact that Array does not dispute). *See* D.I. 18 at 2. The facts here are similar to those in *UCB*, where the Court found no undue prejudice because the defendant was unlikely to come to market before the expiration of the stay. 2017 WL 4310860, at *2. Even if the stay in this case lasts for years pending any appeal of the *Alembic* construction, Array will not be unduly prejudiced because it will have its "determination of its patent rights" long before Teva comes to market.

Entering immediate judgment, and forcing Teva to address the *Alembic* construction on appeal, would prejudice Teva. Teva did not participate in the briefing or argument on that claim construction. Array has provided no identification of asserted claims or contentions concerning Teva's proposed generic product. No discovery has taken place in this case. Importantly, none of the underlying record upon which the Court relied in rendering its claim construction is part of the record in this case. Array asserts that the claim construction could simply be appealed in this case, but offers no explanation of how that could be efficiently accomplished. Nor does Array explain why it would not be more appropriate to stay this matter and allow the parties who briefed and argued the substantive claim construction issues to address those questions on appeal. There is no prejudice to Array from a stay in this case.

III. CONCLUSION

For the foregoing reasons, Teva respectfully requests that the Court stay this action pending resolution of any appeal of the Court's claim construction order in the related *Alembic* litigation.

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